K011862 Page 1 of 2

JUL 12 2001

510(k) Summary

Sponsor Information

Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E700
Golden, CO 80401
303-279-7500

Contact Person: Jeff Hill, RA/QA Coordinator

This 510(k) summary was prepared on June 11, 2001.

Device Identification

This special 510(k) is for a modification to the Denver Ascites Shunts and Denver PAK: Percutaneous Access Kit with Ascites (peritoneovenous) Shunt. The modification is a change in supplier for the tubing used to fabricate the peritoneal cottagers and the venous catheter of the surgically-placed shunts. The tubing made by the new supplier is very similar in formulation and physical properties to the tubing that had been used previously. The shunt with the tubing produced by the new supplier has been found to be substantially equivalent to the legally marketed shunt.

Intended Use

The Denver Ascites Shunts are used to symptomatically treat intractable ascites due to disseminated malignant disease, hepatic disease, and other underlying diseases and conditions that cause ascites fluid to build up in the abdominal cavity.

Device Description

The Denver Ascites shunt is made of a fenestrated peritoneal catheter, which collects the ascites fluid; a valved pump chamber, which allows flow from the peritoneum to the venous system but no reverse flow; and a venous catheter, which discharges the ascites fluid into the central venous system.

The fluid transfer happens automatically when the patient lies down, because of the pressure differential between the peritoneal cavity and the central venous system. The spontaneous rate of transfer can be supplemented by manual pumping of the chamber. Pumping may also help limit buildup of fibrinous debris in the chamber.

All components of the shunt are made of silicone rubber.

Summary of the change

The change that was the subject of the special 510(k) was a change in supplier for the tubing that forms the peritoneal catheters of all ascites shunts and the venous catheter of the surgically-placed shunts.

The new tubing has been found to be equivalent to the previous tubing by

1. Comparing the dimensional specifications
2. Comparing the physical property specifications
3. Testing to ensure that the bond strength between the tubing and the shunt body remains within specification.
4. Testing to ensure that the friction fit between the tubing and the nylon connectors used in shunt revision is within specifications.
5. Testing to ensure that the new tubing responds as expected to a surface treatment process that reduces surface friction.
6. Testing to verify that the tubing meets acceptable standards for biocompatibility for a device in long-term contact with blood.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Ms. Bonnie B. Vivian
President and CEO
Denver® Biomedical, Inc.
14998 W. 6th Avenue, Bldg. E-700
GOLDEN CO 80401

Re: K011862
Denver® Ascites Shunt and Percutaneous
Access Kit with Ascites Shunt
Dated: June 11, 2001
Received: June 14, 2001
Regulatory Class: II
21 CFR §876.5955/Procode: 78 KPM

Dear Ms. Vivian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011862

Device Name: Denver Ascites Shunts

Indications For Use:

Peritoneo-venous shunting is indicated for patients with:

- chronic liver disease whose ascites has not responded to surgical correction of their portal hypertension nor to standard medical management.
- persistent ascites who are not considered candidates for portal-venous shunting.
- persistent ascites that is non-responsive to standard medical management.
- primary or metastatic intra-abdominal neoplasms with massive ascites to help relieve intra-abdominal pressure.

Peritoneo-venous shunting should also be considered for patients with hepatorenal syndrome, chylous ascites and idiopathic ascites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011862

Prescription Use ✓
(Per 21 CFR 801.109)